

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF
WASHINGTON



JUN 24 2021

AT SEATTLE
CLERK U.S. DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
BY DEPUTY

UNITED STATES of AMERICA, ex rel.
ANDREW P. MALLON

Plaintiff,

vs.

ATHIRA PHARMA, INC.

Defendant

Case No. 2:21-cv-00853 RSL

**FILED UNDER SEAL
PURSUANT TO 31 U.S.C.
§3730(b)(2)**

JURY TRIAL DEMANDED

COMPLAINT

Plaintiff Relator Dr. Andrew P. Mallon on behalf of the United States of America files this Complaint in camera and under seal, which will be pursued through his attorneys, against Defendants.

The Complaint in this qui tam action asserts violations of the False Claims Act ("FCA"), 31 U.S.C. §§ 3729 et seq. The FCA mandates that the Complaint be filed under seal, 31 U.S.C. § 3730(b)(2). That section of the statute provides: "The complaint shall be filed in camera, shall remain under seal for at least 60 days, and shall not be served on the defendant until the court so orders." 31 U.S.C. § 3730(b)(2).

INTRODUCTION

1. This is an action to recover treble damages and civil penalties on behalf of the United States of America arising from false and/or fraudulent records, statements and

claims made and caused to be made by Defendant and/or its agents and employees, in violation of the federal False Claims Act, 31 U.S.C. §§ 3729 et seq. ("the FCA").

2. This action seeks to recover millions of dollars acquired by Defendant from the United States Government, including, but not limited to the application and award of a NIH grant entitled "A randomized, placebo-controlled, double-blind study to evaluate safety and efficacy of NDX-1017 treatment in Alzheimer's dementia patients", award number 1R01AG068268-01 for \$15.2m.

3. In addition, the action seeks damages for grant applications that were applied for containing willful material false statements that were not funded, including, but not limited to the application R42 AG055246-01 "Small molecule neurotrophic factor (HGF) allosteric activator for the treatment of age-related cognitive decline" for \$1,722,230.

4. The FCA was enacted during the Civil War, and was substantially amended in 1986, and again in 2009 and 2010. Congress amended the FCA in 1986 to enhance the Government's ability to recover losses sustained as a result of fraud against the United States after finding that fraud in federal programs was pervasive and that the FCA, which Congress characterized as a primary tool for combating government fraud, was in need of modernization. The amendments create incentives for individuals to come forward with information about fraud against the Government without fear of reprisals or Government inaction, and enable the use of private legal resources to prosecute fraud claims on the Government's behalf.

5. The FCA prohibits, inter alia: (1) knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval; and (2) knowingly making

or using, or causing to be made or used, a false or fraudulent record or statement material to a false or fraudulent claim. 31 U.S.C. §§3729(a)(1)(A), (B). Any person who violates the FCA is liable for a civil penalty of up to \$11,000 for each such claim, plus three times the amount of the damages sustained by the Government. 31 U.S.C. §3729(a)(1)(A) (as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 [28 U.S.C. §2461 note; Public Law 104-410]).

6. In 2009, Congress amended the FCA to clarify that a "claim" includes "any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property that (i) is presented to an officer, employee, or agent of the United States; or (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest " 31 U.S.C. §3729(b)(2).

7. The FCA allows any person having information about an FCA violation to bring an action for himself and the Government, and to share in any recovery. The FCA requires that the complaint be filed under seal for a minimum of 60 days (without service on the defendant during that time) to allow the Government time to conduct its own investigation and to determine whether to join the suit.

8. Based on the foregoing laws, *qui tam* Plaintiff Relator Andrew P Mallon seeks through this action to recover all available damages, civil penalties, and other relief for the violations alleged herein in every jurisdiction to which Defendant's misconduct has extended.

PARTIES

9. Plaintiff Relator Dr. Andrew P. Mallon (“Dr. Mallon”) is a resident of 32 Riverside Drive in Lincoln, Rhode Island, 02865 and is a PhD scientist, pharmacist and has a lengthy career as a Biotechnology executive. Dr. Mallon has also served the United States Government in the role of an expert reviewer for the Center for Scientific Review looking at grant applications and opining upon their merit. Dr. Mallon is an expert at assessing science for application in commercial development.

10. Defendant Athira Pharma, Inc., formerly known as M3 Biotechnology, is a clinical stage therapeutics company developing regenerative therapies for neurological diseases such as Alzheimer's disease and Parkinson's disease. It is publically traded on the NASDAQ stock exchange as “ATHA”. It is headquartered at 18706 North Creek Parkway, Suite 104, Bothell, WA 98011. It is organized under the laws of the State of Delaware.

11. At all times relevant hereto, Defendant acted through its agents and employees, and the acts of Defendant's agents and employees were within the scope of their agency and employment. The acts alleged in this complaint were, on information and belief, established and/or ratified at the highest corporate levels of Defendant.

Jurisdiction and Venue

12. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730.

13. Relator qualifies as the “original source” of the information on which the allegations or transactions in this Complaint are based. Before filing this action, Relator voluntarily disclosed to the Government the information on which the allegations or transactions in this Complaint are based. Additionally, Relator has direct and independent knowledge about the misconduct alleged herein and that knowledge is independent of and materially adds to any publicly disclosed allegations or transactions relevant to his claims.

14. Venue in this district is proper pursuant to 28 U.S.C. § 1391 because the Defendant’s business is located in Washington State.

ALLEGATIONS

15. The NIH is a branch of the Department of Health and Human Services that funds research grants. The NIH published an R01 grant opportunity sponsored by the National Institute on Aging (NIA) and National Institute of Nursing Research (NINR) entitled “Early Stage Clinical Trials for the Spectrum of Alzheimer's Disease and Age-related Cognitive Decline (R01 Clinical Trial Optional)”. Funding Opportunity Announcement (FOA) Number PAR-18-877.

16. The Defendants applied for this grant and referenced data from papers that demonstrated the effectiveness of their scientific approach, the activity of their products and the scientific ability and acumen of their staff, officers, and collaborators.

a. “Hepatocyte growth factor mimetic protects lateral line hair cells from aminoglycoside exposure” *Frontiers in Cellular Neuroscience* (2015) - Pubmed: 25674052 doi: 10.3389/fncel.2015.00003 issn: 1662-5102 Authors: Phillip M. Uribe ,

Leen H. Kawas (author has email) , Joseph W. Harding , Allison B. Coffin (author has email).

b. “Evaluation of metabolically stabilized angiotensin IV analogs as procognitive/antidementia agents” The Journal of pharmacology and experimental therapeutics (2013) Pubmed: 23055539 doi: 10.1124/jpet.112.199497 issn: 1521-0103 issn: 0022-3565. Authors: Alene T. McCoy , Caroline C. Benoist , John W. Wright , Leen H. Kawas , Jyote M. Bule-Ghogare , Mingyan Zhu , Suzanne M. Appleyard , Gary A. Wayman , Joseph W. Harding (Author has email).

c. “Mimics of the dimerization domain of hepatocyte growth factor exhibit anti-Met and anticancer activity” The Journal of pharmacology and experimental therapeutics (2011). Pubmed: 21859930 doi: 10.1124/jpet.111.185694 issn: 1521-0103 issn: 0022-3565. Leen H. Kawas (author has email), Brent J. Yamamoto , John W. Wright (author has email), Joseph W. Harding (author has email).

d. “The Procognitive and Synaptogenic Effects of Angiotensin IV–Derived Peptides Are Dependent on Activation of the Hepatocyte Growth Factor/c-Met System” The Journal of pharmacology and experimental therapeutics (2014) ;Pubmed: 25187433 doi: 10.1124/jpet.114.218735 issn: 1521-0103 issn: 0022-3565. Authors: Caroline C. Benoist , Leen H. Kawas (author has email), Mingyan Zhu , Katherine A. Tyson , Lori Stillmaker , Suzanne M. Appleyard (author has email), John W. Wright (author has email), Gary A. Wayman (author has email), Joseph W. Harding (author has email).

e. “Development of angiotensin IV analogs as hepatocyte growth factor/Met modifiers”. The Journal of pharmacology and experimental therapeutics (2012). Pubmed: 22129598 doi: 10.1124/jpet.111.188136 issn: 1521-0103 issn: 0022-3565. Authors:

Leen H. Kawas (author has email), Alene T. McCoy , Brent J. Yamamoto , John W. Wright (author has email), Joseph W. Harding (author has email).

17. In December 2020, Defendants learned that they would be awarded a grant from the National Institutes of Health, or NIH, for Alzheimer's research in the amount of \$15.2 million

18. The grant was reviewed by expert members of the Study Section Special Emphasis Panel [ZRG1-BBBP-B(55)R] 'The Biobehavioral and Behavioral Processes (BBBP)', which considers applications on biobehavioral and behavioral processes across the lifespan.

19. The review of this grant was based upon the submission materials provided by the applicant in their grant application, and referenced explicitly or implicitly, including but not limited to the papers above.

20. The scientific expert members of the Study Section are tasked by the NIH to independently review the merit of the grant application and advise the NIH about funding. A score is generated by the review committee and those applications that are best scored are selected for funding depending upon available funds. The score is based upon the demonstrable scientific merit of the proposal.

21. The grant(s) referenced the data in the aforementioned papers directly and indirectly in order to demonstrate the effectiveness of the product. For example, the 1R01AG068268-01 grant 'Abstract' section stated "In in vitro studies, NDX-1017 has been shown to activate the target HGF system and induce downstream effects to promote spinogenesis and synaptogenesis, enhance long-term potentiation, and protect neurons from oxidative stress. In animal studies, NDX-1017 has been shown to restore synaptic

loss, regenerate neurons, and reverse cognitive and functional impairment, in 6-OHDA model of neurodegeneration, as well as scopolamine and aged animal models of dementia.”

22. In addition, the biosketches and other available information of the Defendant personnel associated with the grant reference these papers and the data therein.

23. The reviewers and thereby the NIH and US base their funding decision on the merit of the data presented. It is the primary material fact(s) that is the basis of assessing whether a scientific product is meritorious and heavily influences score.

24. The data was critically relied upon in order to make a decision to fund the 1R01AG068268-01 grant. This is in contrast to the R42 AG055246-01 that was specifically denied funding because the Relator uncovered evidence of falsified data, exemplifying how the reliance on the veracity of the Defendants submissions and information was material to the government’s damages.

25. The Defendants submitted the data and referenced data; and allowed the data to be published with the intention and assurances that the data was true even up to 5 years after they were explicitly notified of discrepancies in the data in 2016 by the Relator.

26. In fact, the papers and grants contained falsified research results.

27. The Plaintiff Relator first and originally detected and reported the falsification of the data in these papers in approximately April to July 2016 whilst serving as an expert reviewer on Emerging Technologies and Training in Neurosciences IRG – ETTN. The Emerging Technologies and Training in Neurosciences (ETTN) IRG reviews

crosscutting neuroscience grant applications that focus either on the application of emerging technologies to neuroscience problems or on training in the neurosciences.

28. Defendants, using the prior name of “M3 BIOTECHNOLOGY, INC.” submitted a grant entitled ‘Small molecule neurotrophic factor (HGF) allosteric activator for the treatment of age-related cognitive decline” under the FOA Title: PHS 2015-02 OMNIBUS SOLICITATION OF THE NIH FOR SMALL BUSINESS TECHNOLOGY TRANSFER GRANT APPLICATIONS (PARENT STTR [R41/R42]).

29. Upon review, Relator detected falsification and fabrication of the data, described and illustrated it, and relayed this fact to the NIH administrative officers, the Defendants, the University of Washington, and their investors. The Relator was proactive in warning the Defendant in writing of the severe consequences and dangers of using false data.

30. In addition, the Relator also communicated his findings to the authors via the “Pubpeer” internet system that allows reviewers to describe and communicate problems with the data directly to the authors listed. In the papers listed above it states “(author has email)” after certain authors. These authors were emailed the comments.

31. The Relator explicitly relayed the following statements to the Defendants via the NIH in addition to other correspondence and communication:

- a. “Concerns about rigor of the data in the research undermined confidence in the proposal.”
- b. “Concerns about data [] in three papers authored by the PI and other Key Personnel: “Mimics of the dimerization domain of hepatocyte growth factor exhibit anti-Met and anticancer activity” and "The pro-cognitive and

exhibit anti-Met and anticancer activity” and “The pro-cognitive and synaptogenic effects of angiotensin IV-derived peptides are dependent on activation of the hepatocyte growth factor/c-Met system” and “Development of angiotensin IV analogs as hepatocyte growth factor/Met modifiers”. These concerns raised questions about the rigor of the research and the strength of the patent. This was a significant concern.”

- c. “Western blots provided in Figure 2 were without loading controls such as Actin or Tubulin. Total Met levels suggest that there may have been loading errors (e.g. lane 2 and 5) and it is not clear if the p-Met results were re-weighted. Indeed, it is unclear if the T-Met and P-Met are from the same experiments because the bands are of a different orientation. These concerns reduced enthusiasm for the grant.”

32. As detailed in the communications to the Defendants and as enunciated in the Pubpeer postings by the Relator, the data in question had clear evidence of fabrication and falsification that cannot be explained except by a calculated action to deceive.

33. For example in Figure 4 of “Development of angiotensin IV analogs as hepatocyte growth factor/Met modifiers”, scientific data that consisted of pictures of photographic film were fabricated by copying additional ‘bands’ on top of the original data to fabricate the result. This was made obvious to the expert relator by the presence of a different shaded ‘box’ around the added band and the different length it had.

34. For example, in “The Procognitive and Synaptogenic Effects of Angiotensin IV–Derived Peptides Are Dependent on Activation of the Hepatocyte Growth Factor/c-Met System”; Figure 2C. The Plaintiff Relator detected again the

presence of clear ‘cut and paste’ lines marking where new data had been introduced. The Plaintiff Relator also detected manipulations and inconsistencies in the data that indicated the data as false.

35. For example, in “Mimics of the dimerization domain of hepatocyte growth factor exhibit anti-Met and anticancer activity”. Similarly, autorad data was taken and manipulated by flipping and stretching to fabricate data that was falsely represented as other data.

36. For example, in “Nanoscale mapping of the Met receptor on hippocampal neurons by AFM and confocal microscopy”. Figure 4, autorads data was fabricated by copying data from another source on top of the original data. In Figure 2D, data in the figure was enhanced by copying and reproducing parts of the figure to falsify the result.

37. The Defendants knew that the reviewers of the grants would have relied upon the veracity of their research and their reputation for honesty as critical material facts to form an opinion on funding the grant application(s).

38. The Defendants knew that the data in the papers and grants had been falsified.

39. Due to the communication in 2016 by the Relator of the specific evidence of fabricated and falsified data, the Defendants knew that the data was not true or reliable and should not have been presented to reviewers as true or reliable.

40. Furthermore, the Defendants knew that the person or persons who generated the fabricated and falsified data were not honest.

42. The Defendants knew that they should explicitly identify concerns of research integrity, undertake annual investigations and officially report such findings to the Office of Research Integrity and other appropriate agencies.

43. By depriving the reviewers and NIH officers of this information and falsely representing their research as being true and their researchers honest and competent, the Defendants knew that a funding decision and continual provision of funds against claims would be made based upon these material falsehoods.

44. The Defendants harmed the United States of America by being awarded, repeatedly claiming and spending funds based upon intentional false statements that were material to the funding decision and omission of information that would have affected the advice of reviewers and decision of NIH officers.

45. The Defendants received the Federal grant funding as recorded by the NIH RePORTER online database.

Count I
Federal False Claims Act
31 U.S.C. §§ 3729(a)(1)(A) and (a)(1)(B)

46. Relator repeats and realleges each and every allegation contained in the preceding paragraphs, as though fully set forth herein.

47. This is a claim for treble damages and penalties under the Federal False Claims Act, 31 U.S.C. §§ 3729, et seq., as amended.

48. Through the acts described above, Defendants have knowingly presented or caused to be presented, false or fraudulent claims to officers, employees or agents of the United States, within the meaning of 31 U.S.C. § 3729(a)(1)(A).

48. Through the acts described above, Defendants have knowingly presented or caused to be presented, false or fraudulent claims to officers, employees or agents of the United States, within the meaning of 31 U.S.C. § 3729(a)(1)(A).

49. Through the acts described above, Defendants have knowingly made, used, or caused to be made or used, false or fraudulent records and statements, and omitted material facts, to get false and fraudulent claims paid or approved, within the meaning of 31 U.S.C. § 3729(a)(1)(B).

50. The United States, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay claims that would not be paid but for Defendants' unlawful conduct.

51. As a result of the Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

52. Additionally, the United States is entitled to the maximum penalty of \$11,000 for each and every false and fraudulent claim made and caused to be made by Defendants arising from their unlawful conduct as described herein.

Prayer for Relief

Wherefore, Relator prays for judgment against the Defendants as follows:

1. That Defendants cease and desist from violating the False Claims Act, 31 U.S.C. §§ 3729 et seq.
2. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the United States and the States have sustained because of Defendants' actions, plus a civil penalty of \$11,000 for each violation of 31 U.S.C. § 3729.

3. That Relator be awarded the maximum amount allowed pursuant to 31 U.S.C. §3730(d).
4. That Relator be awarded all costs of this action, including attorneys' fees, costs and expenses; and
5. That Relator recovers such other and further relief as the Court deems just and proper.

Demand for Jury Trial

6. Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby demands a trial by jury.

Respectfully submitted,



Andrew P Mallon
32 Riverside Dr
Lincoln, RI 02865
Tel: (401) 345-5979
Email: andrewmallon21a@gmail.com

Dated: June 22, 2021

ANDREW MASON
32 RIVERSIDE DR
LINDEN RI 02835

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
[IN CAMERA AND UNDER SEAL]

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